



AESCULAP[®]

JUL 18 1997

K971310

510(k) Summary of Safety and Effectiveness in Accordance with SMDA of 1990

Aesculap Jet Irrigation System

April 7, 1997

Submitted by: Aesculap[®], Inc.
1000 Gateway Blvd.
So. San Francisco, CA 94080
Contact: Mary Ellen Holden
Phone: (415) 876-7000 x348
FAX: (415) 589-3007

Product: Aesculap Jet Irrigation System

Common Name: Irrigation System

Intended Use

The Jet Irrigation System presented in this submission is designed for use with Aesculap's Bipolar Coagulator (GN060). The Jet Irrigation Unit (GN090) delivers either precisely measured drip irrigation or a continuous jet stream of irrigation to the tip of Aesculap's Bipolar Irrigation Forceps (GK840R - GK847R). The use of drip irrigation serves to prevent overheating and tissue adherence during bipolar coagulation. Continuous "jet" irrigation provides a clearer visual field.

Technological Characteristics

Aesculap's Jet Irrigation System is substantially equivalent to Codman's Malis Irrigation System in design features and technological characteristics.

Both the Jet Irrigation System and the Malis Irrigation System are designed to be used in conjunction with a Bipolar Coagulator. They provide delivery of precisely controlled irrigation to the tip of bipolar irrigation forceps.

Performance Standards

No applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, Aesculap's Jet Irrigation Unit complies with the requirements of Underwriters Laboratories, Inc., for medical and dental equipment.

In addition, the Bipolar Irrigation Forceps meet the requirements of IEC 601-2-18 (Medical electrical equipment, Part 2: Particular requirements for the safety of endoscopic equipment.)

The Jet Irrigation System will be manufactured in accordance with ISO and German Din Standards. Furthermore, Aesculap AG has received ISO 9001 certification.

Substantial Equivalence

Aesculap's Jet Irrigation System shares similar features and function with corresponding devices distributed by Aesculap and Codman.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Mary Ellen Holden
Regulatory Compliance Associate
AESCULAP® , Inc.
1000 Gateway Boulevard
South San Francisco, California 94080-7030

JUL 18 1997

Re: K971310
Trade Name: Aesculap Jet Irrigation System
Regulatory Class: II
Product Code: GEI
Dated: July 3, 1997
Received: July 7, 1997

Dear Ms. Holden:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

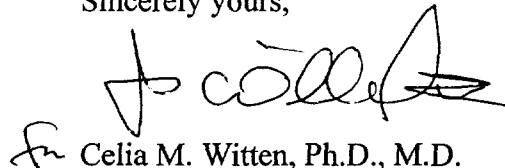
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): N/A
K971310

Device Name:
Aesculap Jet Irrigation System

Indication for Use:

Aesculap's Jet Irrigation System is designed for use with Aesculap's Bipolar Coagulator. The Jet Irrigation System delivers either precisely measured drip irrigation or a continuous jet stream of irrigation to the tip of Aesculap's Bipolar Irrigation Forceps. The use of drip irrigation serves to prevent overheating and tissue adherence during bipolar coagulation. Continuous "jet" irrigation provides a clearer visual field.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K971310

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)